

Ref #5

28 APR 1987

Safer, Inc.
60 William Street, Suite G-20
Wellesley, MA 02181

Gentlemen:

Subject: Safer Insecticidal Soap Concentrate
EPA Registration No. 42697-1
Safer Flea Shampoo For Dogs
EPA Registration No. 42697-6
Safer[™] Flea Guard Concentrate
EPA Registration No. 42697-15
Your Letter Dated February 12, 1987

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable for the reasons given below.

EPA Registration Nos. 42697-1 and 42697-6

1. The product (EPA Registration No. 42697-6) should be labeled for eye irritation Toxicity Category III. Alternatively, data should be submitted to demonstrate that this product falls in Toxicity Category IV for this exposure route.
2. A [REDACTED] study on the concentrate (EPA Registration No. 42697-1) has indicated the concentrate to be a nonsensitizer. Since this product is a dilution of the concentrate, it can be classified as a Nonsensitizer.
3. We have no acceptable acute [REDACTED] data on this product or the concentrate (EPA Registration No. 42697-1). Considering the [REDACTED] these products should be labeled for acute Toxicity Category III. Alternatively, data should be submitted to demonstrate that these products fall under Toxicity Category IV for oral exposure.

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CONCURRENCES

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Insect Ingredient Information is not Included

4. In conclusion, the following label changes should be made in precautionary labeling (note some of these changes are already on the concentrate label, EPA Registration No. 42687-1):

- a. Add "May cause eye irritation. Avoid contact with eyes or clothing" to Precautionary Statements.
- b. Add Statement of Practical Treatment (or First Aid) for oral and eye exposures. These should read something like the following:

If Swallowed - Call a physician or Poison Control Center. Drink a large quantity of milk, egg whites, or water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If In Eyes - Flush with plenty of water. Get medical attention if irritation persists.

EPA Registration No. 42697-15

1. Precautionary labeling on revised label should be changed as follows:
 - a. Change "avoid eye contact" to Avoid contact with eyes or clothing."
 - b. Add to Precautionary Statements:

Do not use or store near heat or open flame.
 - c. Add a physical and chemical hazard statement to the label.
2. A dermal sensitization study on the concentrate (EPA Registration No. 42697-1) has indicated the concentrate to be a nonsensitizer. Since this product is similar to the concentrate, it can be considered a Nonsensitizer.
3. We have no acceptable acute toxicity data on this product. Considering the [REDACTED] this product should be labeled for acute oral Toxicity Category III. Alternatively, data should be submitted to demonstrate that this product falls under Toxicity Category IV for this exposure route.

Inert Ingredient Information is not Included

4. The Statement of Practical Treatment or First Aid statement should be something like the following:

If Swallowed - Call a physician or Poison Control Center. Drink a large quantity of milk, egg whites, or water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If In Eyes - Flush with plenty of water. Get medical attention if irritation persists.

Sincerely yours,



William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)